

MTLF Forum Report

ECONOMICS VS INNOVATION

When Does Collaboration Become Conflict of Interest?

June 13-14, 2006
Boston, MA



Harvard Medical School, aerial view of quad



Medical Technology
Leadership Forum

What is the Medical Technology Leadership Forum?

The Medical Technology Leadership Forum (MTLF) was founded in 1996 to bring together members of the medical technology community, including innovative bioengineers, physicians, research institutions and universities, health plans, manufacturers and patient organizations. MTLF Forums include key leaders in public policy to promote dialogue and debate about policy issues of pressing interest to the medical technology community.

In 2005, MTLF moved its operations to the University of Minnesota under the leadership of Professor Susan Bartlett Foote. MTLF continues its tradition of inquiry into important technology policy issues. A Board of Advisors, chaired by former Senator David F. Durenberger, assists MTLF in the identification and implementation of MTLF projects.

Forum reports from our meetings have made a contribution to public policy on a wide range of issues. MTLF receives support from sustaining contributors who have committed to three years of funding, annual contributors, and sponsors—interested organizations who support selected Forums. Forums have been held at leading academic institutions across the country. MTLF also holds an Annual Capitol Forum in Washington, D.C., where participants can dialogue with important policy leaders from all branches of government.



**Medical Technology
Leadership Forum**

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Introduction

MTLF held its first Summit on Conflict of Interest in July of 2001 at Stanford University. The Stanford Summit brought together academics, inventors, government regulators, clinicians, and device companies to examine the issues and make recommendations. The focus at Stanford was the academic/industry interface. To revisit the issue five years later, the MTLF Forum traveled to Harvard University, one of the world's leading research institutions, to once again study the issue, and to explore the changes that have occurred in the last five years. MTLF invited leaders from academia, the device industry, clinicians, and government officials to share their views. Our hosts included Partners HealthCare, the Center for the Integration of Medicine and Innovative Technology (CIMIT), the Brigham and Women's Hospital, and Harvard Medical School.

Managing conflict of interest issues in the area of medical technology innovation is a challenge. **Professor Ken Keller, Board member of MTLF and President Emeritus of the University of Minnesota**, noted in his introductory remarks that this problem is one that does not go away. He commented that conflict of interest calls to mind the myth of Sisyphus pushing the rock up the hill or Don Quixote tilting at windmills. **Dr. Thomas Fogarty, world renowned inventor and surgeon**, reminded us that conflict of interest is difficult to define, is inherent in the role of physician/inventor, and can't be avoided.

Despite the continuing challenges, MTLF undertook its exploration of conflict of interest issues again in 2006. This Report attempts to capture the provocative and stimulating presentations and dialogue. Part I sets the stage by summarizing the presentations of our two distinguished keynote speakers – **Dr. Jerome Kassirer, Professor of Medicine at Tufts University** and **Dr. Samuel O. Thier, Professor of Medicine and Professor of Health Policy at Harvard University School of Medicine**. Part II recounts the changes that have occurred in the medical technology environment in the last five years. Part III explores responses to those changes, in both the private and public sectors, as described by the Forum speakers. Part IV summarizes the Stanford recommendations in light of the changed and changing environment.



MTLF Director



Dr. Thomas Fogarty



*Dr. Jerome Kassirer,
Dr. James Mongan,
Hon. David Durenberger,
Dr. Lawrence Cohn and Professor
Susan Bartlett Foote*

I. Setting the Stage

The goal of the program, “Economics versus Innovation: When Does Collaboration Become Conflict of Interest?” was to look at how to balance collaboration and conflict in the medical technology community. Two much admired physician leaders, **Dr. Jerome Kassirer, Professor of Medicine at Tufts University** and **Dr. Samuel O. Thier, Professor of Medicine and Professor of Health Policy at Harvard University School of Medicine** offered thoughtful and contrasting perspectives on the program’s theme.

In his keynote address, **Dr. Kassirer** shared his view that conflict of interest is eroding public trust both in the medical profession and the drug and device industry. The loss of confidence in medicine is due to complex financial incentives in practice, referrals to self-owned facilities, unseemly advertising, and perceived undue influence of industry on physicians, among other factors. The public perceives that the industry jiggers study results, fails to publish unfavorable results, suppresses data on risks, and engages in profiteering and aggressive marketing tactics. In the last decade, it has become harder to find physicians who are not co-opted by the drug and device industry. Citing a series of studies, he noted that physician bias is affected by financial relations, compromises the integrity of study results and ultimately harms patient interests.



Dr. Jerome Kassirer

Kassirer sees the balance weighted down by conflicts, while Thier fears a focus on conflict obscures the upside of collaboration.

Kassirer articulated a series of four principles:

- 1) financial considerations must never compromise physician decisions;
- 2) medical information should be free of bias from financial inducements;
- 3) the profession should be accountable for the high cost of care; and
- 4) all financial arrangements should be open and transparent.

These principles should guide the evaluation of relationships.

However, Dr. Kassirer provided a quote from his book, *On the Take: How Medicine’s Complicity with Big Business Can Endanger Your Health*: “Medical devices save lives and improve life’s quality... To a substantial extent, our free enterprise system and the promise of profits has encouraged physicians, entrepreneurs and commercial enterprise to invest their time and capital in the search of new modes of diagnosis and therapy. It would be counterproductive to inhibit this inventive spirit.”

Thus, Kassirer does not condemn all invention driven by the profit motive. However, in the pursuit of a balance in the face of enormous contributions of industry-academia collaborations and the complications and costs associated with undue industry influence on academic physicians, he offered a series of prohibitions to keep doctors off the slippery slope of conflict. He warned of the limitations of disclosure, and the challenges presented by surveillance of these conflicts. He closed by recognizing that there is no situation free of conflict, but that unless we aggressively address and prevent undue influence, the public will continue to lose confidence in the medical profession as well as the medical device and drug industries.

Dr. Thier, who presented the luncheon address, chose to emphasize the value of collaboration rather than threats posed by conflict of interest. He said: “My concern is that we have spent an enormous amount of time in the last five to ten years trying to prevent conflict of interest and not nearly as much time to maximizing the upside of collaboration which I believe is one of our primary responsibilities.” Collaboration can provide intellectual capital to exploit in the interests of the public’s health which is the goal.

Dr. Thier debunked several myths, including the discontinuous view of industry/university collaboration. The old view was that universities did basic science and industry just developed it. Using biotechnology as an example, he noted that much of the basic work is now done by industry and that university/industry collaboration provides synergies to exploit those technologies. Dr. Thier praised the development of long term relations between scientists in industry and academia. Good partnerships will get answers to medical problems more quickly and with less expense than operating in silos.

He commented that drugs and devices all have some side effects and that we need to more appropriately define the level of safety that the public should expect from these products. He



Dr. Samuel Thier

“It is not necessarily the case that if you are biased, you are wrong. It is also not necessarily the case that if you are not conflicted, you are right.”

also noted that science should drive decisions. “It is not necessarily the case that if you are biased, you are wrong. It is also not necessarily the case that if you are not conflicted, you are right.” Science should be able to answer the questions.

He warned not to focus excessively on conflict of interest, or in the flow of money, at the expense of the primary medical goals to prevent, diagnose and treat disease. However, he did note that “to the degree that conflict of interest interferes with the ability to do that, it must be addressed. To the degree it interferes with the public trust, it must be addressed.” When he served as President of the Institute of Medicine, the organization embraced conflict of interest, tried to balance interests and get to consensus even when there were people with biases. Ultimately, science, however, must prevail.

Our two distinguished speakers approach the issue of conflict versus collaboration from two different starting points. Kassirer sees the balance weighted down by conflicts, while Thier fears a focus on conflict obscures the upside of collaboration. However, both recognize that conflict and the perception of conflict must be managed to protect the public trust. It is to the issue of managing conflict, then, that we must now turn.

CONFLICT OF INTEREST FROM 2001-2006

How has the Issue Changed in the Last Five Years?

Rapid Growth in Medical Technology/ Rising Costs of Health Care

Several speakers recognized that there has been rapid growth in all forms of medical technology, including drugs, devices and biotechnology. The ubiquity of all forms of medical technology, including press coverage of breakthrough innovations, has raised the profile of medical technology in the public consciousness. There has also been rising costs of health insurance and growing numbers of uninsured individuals in the United States. Rising costs also have raised public concerns.

The growth of invention, the rising costs of health care services, and changing organizational structures for delivery, including the rise of for-profit health institutions, has raised the financial stakes in health care. The costs to bring a medical technology can run into the millions of dollars, with significant risks and substantial potential rewards as well. These risks and rewards increase the pressure to achieve market success for all components of the system.

Evolution of a More Complex Economic Environment

As noted by **Professor Fran Miller, Boston University**, our health care system is based on a competitive model with a number of sources of regulation. The last five years have seen the evolution of a much more complex economic environment. Professor Miller described the corridor of permissible conduct, including fraud and abuse issues, antitrust issues, gainsharing, and stark constraints against self referral, to name a few. **Christopher White, the General Counsel of AdvaMed**, the device industry's largest trade association, described the challenges of fresh applications of older statutes that implicate virtually every relationship in the device industry. **David Nexon, Senior Executive Vice President at AdvaMed**, offered a detailed analysis of the challenges of gain-sharing concepts.

Growing Media Attention to Medical Technology Issues

In the last few years, there has been growing media attention to controversies about the ethical and financial dimensions of conflict. In 2005-06, the South Korea stem cell research fraud, disclosures about the risks of Merck's Vioxx



Professor Fran Miller

and other related drugs, the ICD failures and concerns about FDA's oversight, and allegations about the Cleveland Clinic's conflicts of interest in investments and research all caused controversy and concern. While there is certainly debate about the merits of many of these controversies, it is clear that adverse and critical press has increased in intensity and scope in the last five years. One may ask whether the media attention erodes public trust, or whether the media attention simply reflects unacceptable conduct to which the public reacts. Whatever the reasons, however, it is clear that adverse media attention affects the public trust.

The Impact of Globalization

Globalization presents another potential set of issues. Are ethical and regulatory protections for research subjects accepted or implemented in studies in some foreign countries? **Dr. Andrew Wechsler, Professor at Drexler University and Editor, *Journal of Thoracic and Cardiovascular Surgery***, provided examples of questionable informed consent in studies submitted to his journal. The Food and Drug Administration is also concerned with the impact of globalization of clinical trials. **Dr. Scott Gottlieb, Deputy Commissioner for Medical and Scientific Affairs at the Food and Drug Administration** made reference to an FDA initiative that includes a focus on how to design rules for foreign clinical studies (*FDA News*, "FDA Announces New Initiative to Modernize the Regulation of Clinical Trials and Bioresearch Monitoring," June 26, 2006).

III. How Have Relevant Interests Responded?

Many speakers at the Harvard Forum provided their views on these changes and the responses that have occurred as a result. Five years ago, many academic institutions were just beginning to develop institutional rules to govern conflicts of interest in research. Like most research institutions, Harvard Medical School and Partners HealthCare have developed extensive rules that must be followed without exception.

Academic Medicine Perspectives

Dr. John Parrish, Director and Founder of CIMIT, has had intense collaborations with industry. He described one situation where his scientific work on the effects of sun tanning and burning created a market that he then disengaged from, and another where his scientific work on treatment of psoriasis created an industry that changed care.

Dr. Parrish shared the lessons learned over the past years in the implementation of the conflict rules in his institution. One important insight from a career working at the interface of scientific research and product invention is that conflicts don't go away. Conflicts of interest are not always about money. There can be other motivations including desire for fame and promotion, or simply to improve patient care. A second important insight was that having rules doesn't resolve the conflict issues because they are very complex. Each institution not only must embrace the complexity, but must understand that every case is unique. Each investigator must be addressed on a case-by-case basis. Each is a case of one. It is important to coach investigators through the conflicts.

Dr. Ronald Newbower, a co-founder of CIMIT and a bioengineer, elaborated on these themes. He noted that there are tremendous tensions in institutions after policies have

been enacted. Development of policies is only the beginning. There are huge challenges in the rule-based management of conflicts. Different players within institutions focus on their own needs – from the trustees, senior administrators, to department chiefs and clinicians doing sponsored research. There can be forces creating divisiveness within the institution. Harvard has a set of rules with no exceptions, fearing that exceptions might lead the institution down a slippery slope. Dr. Newbower cautioned that all slopes are not alike. There are many borderline issues. If researchers think the policies are unreasonable, they can drive disclosure underground.

Dr. Newbower called for processes that respond to special circumstances in a careful and thoughtful manner. He noted that most of the conflict of interest rules look pretty similar from institution to institution. The real challenge now is in the carrying out of those rules. That is where differences become apparent. He recommended a parallel structure to review issues to help investigators understand the reasoning and to see how they can work within the institutional framework. In regard to public trust, Dr. Newbower noted that the public intuitively understands conflict and will fault an institution that ignores that reality. If the institution has a thoughtful process, its lapses will be forgiven. The public can understand that things can go wrong, but will accept it if there are thoughtful ways to evaluate the issues. Creating these processes takes work and few institutions have invested enough effort in this area.

Dr. Robert J. Mayer, Professor of Medicine at Harvard Medical School, serves as chair of the Harvard Medical School standing committee on conflict of interest. Dr. Mayer provided the clinical research perspective. His own research



Panelists (left to right) Dr. Kenneth Keller, Dr. Thomas Fogarty, Dr. John Parrish, Dr. Robert Mayer, Dr. Andrew Wechsler, Dr. Ronald Newbower, Mr. Christopher White



Dr. John Parrish

focuses on oncology. He expressed concern that the rules for clinical trials have changed as financial support for trials has moved from government support to private financing.

The National Cancer Institute (NCI) has moved away from clinical trials and focused on other activities such as the Human Genome Project. He noted that the clinical trial process has been usurped by the pharmaceutical and biotechnology industry. They can get them running faster and are more efficient, but they exercise more control and design the trial to their liking. As he described the situation, industry will design the study in-house or with a consultant not the investigator. Then, investigators and participants are assembled and funding arrangements completed. It is often unclear if there is a true principal investigator and who owns the data developed in the trial.

These changes raise critical questions about the validity of the study in light of the sponsor's role. Is the statistician analyzing the data independent of the sponsor? How certain can anyone be that the toxicity reporting is complete? Who is the true author of the study? Can an investigator who is paid substantially on a retainer be truly objective in analyzing the data? Is disclosure sufficient? Mayer concluded that "there needs to be a true partnership between investigators and industry that is maintained and encouraged, but with clearly defined safeguards to protect individuals from falling prey to conscious and unconscious conflicts of interest by ensuring that what is released to the public is as accurate and complete as possible."

Role of Scientific Journals

Dr. Andrew Wechsler, Professor at Drexler University and Editor of the *Journal of Thoracic and Cardiovascular Surgery*, noted that journals were not discussed at all at the Stanford Summit. Issues of conflict of interest in the journal editing and publishing world are now quite significant. Dr. Wechsler noted that conflict of interest matters in this area because publication in a peer-reviewed journal implies there is

scientific validity, adds credibility to the results of the study and is used to market the superiority of one product over another.

There are many levels of potential conflict in the area of scientific publication. He noted that many authors have conflicts of interest. Many don't want to disclose their potential conflicts because these disclosures can affect the credibility of the study or the authors believe that they can define conflict themselves and make their own disclosure judgments. Echoing some of the observations of Dr. Mayer, Dr. Wechsler noted that in many cases the "author" is not the researcher, but the manuscript is written by the sponsor of the study. Investigators may also have continuing relationships with the manufacturer after publication, which binds the researcher to the sponsor financially beyond the terms of the study period.

Dr. Wechsler also noted that journals themselves have multiple levels of conflict. We don't assess conflicts among the reviewers, who may have personal or industrial relationships that color their judgments. Journals want to have an impact on the field, want advertising revenue to increase, want to build up the subscriber base, and want to sell reprints. Many journals now publish industry-sponsored supplements that appear scientifically valid but are of lesser quality than the parent journal.

Dr. Wechsler commented that journals have not been policemen with the ability to evaluate the disclosures they require, nor have they often punished anyone who fails to disclose. Increasingly, however, journals are developing sanctions, such as barring publication in the journal in the future, for those authors who fail to comply with disclosure requirements.



Dr. Andrew Wechsler



Mr. Christopher White

Industry Responses

Perhaps an area of most significant change has been the response of the device industry to the conflict of interest environment. **Christopher White, General Counsel for AdvaMed, the largest medical device trade association**, explained that conflict of interest has come into sharp focus in the device industry. He noted two key trends in the last two years that have influenced the industry's response. The first was the growth of adverse critical press, that other speakers referenced as well, and the second was the fresh application of older statutes, such as anti-kickback laws and False Claims Act prosecutions to name a few.

AdvaMed has responded to the changing economic environment and the adverse media coverage by taking a leadership role in the industry. AdvaMed has established guidelines to balance the need for innovation and collaboration. Mr. White described the three part infrastructure that AdvaMed has developed internally to educate its members through compliance officers, general counsel groups, and corporate leaders. It has developed a code of ethics to govern economic relationships. It is now working to ensure that member companies are compliant with the code of ethics. He described the new logo license initiative that when displayed will signify that the company has embraced the code and had processes in place to enforce it. Mr. White distributed the code and other materials that the organization has developed. Many of these documents are available on the AdvaMed website (www.advamed.org/).

Physician Responses

Dr. David Halsey, Chair of the American Academy of Orthopedic Surgeons Council on Advocacy and Chair AAOS Project Team on Gainsharing, provided insight into the professional association's effort to develop standards within the profession on economic issues and financial relationships. He noted that the ground is quite unstable with the changing enforcement of statutes, discussed in great detail in

Chris White's presentation. He noted that there are many barriers to overcome. With the issue of gainsharing as an example, Dr. Halsey walked through the processes that AAOS goes through to understand the issues, and to develop mandatory standards that apply to all of its members.

Dr. Halsey's presentation illustrated the challenges that the medical profession faces as the economic environment becomes more complex and the appropriate rules of behavior become more challenging to navigate. AAOS is clearly attempting to tackle the issues head on, to develop credible standards, and to hold its members to those standards through voluntary processes and sanctions.

Government Oversight

Moderator David Durenberger, former U.S. Senator and Chair of the National Institute of Health Policy, opened this session with an overview of the fragmented U.S. health care delivery system. With a primarily private sector system subject to a variety of government oversight, it is challenging to get a coherent regulatory role in this area. Given the multitude of government roles, it was not possible to provide a complete overview of our Forum program. Many agencies within government have roles governing conflict of interest as it applies to its own employees. The National Institutes of Health recently promulgated strict conflict of interest guidelines for its research scientists that caused considerable controversy within the government's scientific community. Some government agencies also have rules about conflicts regarding individuals who serve in various advisory capacities to government. Finally, government agencies have rules regarding the relationships of individuals and organizations that receive government funding or are regulated by the agency in some capacity.



Dr. David Halsey and Dr. Richard Coutts



Dr. Scott Gottlieb

Two officials from two important agencies participated in the Forum. **Dr. Scott Gottlieb, Deputy Commissioner for Medical and Scientific Affairs at the Food and Drug Administration** provided commentary primarily on the role of conflict of interest rules for individuals who serve on FDA's many advisory committees, which is one aspect of FDA's role in conflict of interest. Advisory committees are integral to the FDA functions. They are often called to provide expert review of FDA decision making. Open advisory committees force the FDA to publicly defend its thinking and share how it evaluates the scientific data. Controversies surrounded the conflict of interest of some members of advisory committees has triggered Congressional interest in tightening up the rules. Dr. Gottlieb explained the reasons why the current rules are appropriate from his perspective, and discussed some of the improvements that FDA is currently contemplating. The goal is to make the rules more granular and more transparent. If "conflict" is defined too broadly and enforced too rigidly, FDA will lose access to experts necessary to provide oversight to FDA.

Dr. Gottlieb also noted that FDA is developing new rules on clinical trial oversight through a series of initiatives that have recently been announced.

Ms. Shirley Hicks, Director, Division of Education & Development, Office of Human Research Protections (OHRP), Department of Health and Human Services, provided an overview of the jurisdiction of her agency. Her office, which moved to DHHS from NIH in 2000, provides oversight to protect human subjects who participate in research funded through agencies, such as CDC and NIH, within the DHHS. That includes NIH, CDC among others. She noted that protection of human subjects is necessary in order for the public to have trust in the research process and to encourage participation among the public in clinical trials.

OHRP is now revising its guidances in this area. She noted that regulatory agencies are often reactive and tend to be behind the ball. The challenge is to keep abreast of new technology and the needs of the research community. She commented that research institutions often over interpret the regulations, add burdens that are not necessary, and don't use the flexibility built into the regulations. She described the goals of the agency and the challenges of educating the large and complex research community on compliance with agency regulations and guidances.

While these two officials could cover only a portion of government activity in this area, their presentations provided a window into government's efforts. Government is reactive to public pressure, political pressure, and scientific developments. There is potential for changes in the regulatory environment, manifested in development of new guidances, regulations, and laws. Congressional oversight of the "overseers" at the agency level is always a concern. Agency efforts are chronically under-funded and authority is often divided, fragmented, and limited.



Dr. Kenneth Keller, Dr. Thomas Fogarty, Dr. John Parrish

IV. Conclusion

The 2001 MTLF Report following the Stanford Summit on conflict of interest included five recommendations:

- Respect institutional variation
- Local control is preferred
- Clarify oversight roles
- Improve public understanding of clinical trials
- Reinforce trust in institutions and individuals

What is the status of those recommendations now that five years have passed? What have we learned at the Harvard Forum in terms of the changes that have occurred that affect those recommendations?

Institutional Variation and Local Control

Based on the thoughtful presentations from the clinical research community, it is clear that institutional variation continues. However, it appears that institutional variation has less to do with different conflict of interest rules, and more to do with how those rules are implemented. There are significant challenges for institutions to develop processes to implement the rules. It appears that there has been significant learning within institutions in the last five years as all of them have attempted to manage conflicts in their institutions. Institutional tensions continue and more work needs to be done to improve the processes to manage conflict.

Local control continues. There has been some evolution of oversight for trials sponsored by HHS through the OHRP. However, there has not been standardization and centralization of authority that the Stanford Summit participants feared at the time. Some at the Summit commented that some additional standardization or rules might improve the predictability and compliance.

Clarification of Oversight Roles

The Stanford Summit also sought clarification of oversight roles. Given the fragmentation of government and the multiplicity of institutions in both government and the private sector, it does not appear that greater clarity in oversight has occurred. Government will always be reactive in this regard. Changes are occurring in a piecemeal manner, in response to political, public, and to some extent scientific pressures.

Improve the Public's Understanding of Clinical Trials

There was discussion at Stanford of the need to clarify the public's understanding of clinical trials. The intention at Stanford was to provide greater understanding of the opportunities and the limitations of clinical trials. It appears that this issue

has been swamped by an increasing skepticism by the public, fueled in some part by media coverage of controversies such as Vioxx and the ICDs, about the integrity of clinical trials and the credibility of results. The observations of Drs Mayer and Wechsler support the erosion of clinical trial independence. Controversies involving the integrity of scientific journals fuel this as well, particularly as some journals have had to retract articles after publication when fraudulent conduct has come to light.

Reinforced Trust

The final recommendation involves assuring public trust. As at Stanford, woven throughout the discussion at Harvard were references to public trust. Can we trust physicians to put the patient first? Can we trust physicians, device companies, researchers and scientists to do the right thing? Changes in the financial environment and the role of money in health care have exacerbated the challenges identified five years ago. Research institutions have made great strides in the development of rules to manage conflict, but they still struggle with how to implement their own rules. Professional societies and the device industry appear to have taken great strides to define their roles and develop voluntary standards of conduct. AdvaMed and AAOS should be commended for their substantial efforts in this arena.

Despite these efforts, there appears to be a steady erosion of public trust. The industry, the professions, and the research community need to continue to strive to develop better mechanisms to deal with these issues, always keeping the balance between conflict and collaboration in mind. Progress in the area of defining appropriate rules while searching for confluence of interests for patient care has been made, but the challenges continue. The role of money is a critical, if not the only, factor that all parties must understand and manage. The public needs reassurance that their interest dominates in this arena, although the public needs to be exposed to the value of collaboration in their interest as well. Dr. Samuel O. Thier wisely observed that conflict of interest may be a "hardy perennial" among MTLF issues.

The Harvard Forum provided all of the MTLF participants with fresh insights and new information to help the medical technology community better understand its accomplishments and its continuing challenges to achieve the ideal balance between conflict and collaboration. Perhaps the message is that the search for the balance is an inherent part of the evolution of medical care. Like many hardy perennials, it needs consistent, though not excessive, attention in order to thrive.

Conference Agenda

Tuesday, June 13, 2006

Fairmont Copley Plaza Hotel

6:00 p.m. RECEPTION

7:00 p.m. DINNER

WELCOME

Honorable David F. Durenberger, Chair
Advisory Board, MTLF
James Mongan, M.D., President and CEO,
Partners HealthCare
John Parrish, M.D., Director and Founder,
CIMIT

KEYNOTE

Jerome Kassirer, M.D., Distinguished
Professor, Tufts University School of Medicine

Wednesday, June 14, 2006

Harvard Research Building

7:30 am REGISTRATION AND CONTINENTAL
BREAKFAST

8:15 am WELCOME
Susan Bartlett Foote, Associate Professor,
University of Minnesota; Director, MTLF

8:20-10:30 PERSPECTIVES ON COLLABORATION
AND CONFLICT OF INTEREST FROM
THE HEALTH CARE SECTOR

Moderator, **Professor Kenneth Keller**, Charles
M. Denny, Jr. Professor of Science, Technology
& Public Policy, University of Minnesota

Technology Innovators' Perspective

Thomas J. Fogarty, M.D., Clinical Professor of
Surgery, Stanford University Medical Center
John A. Parrish, M.D., Director and Founder,
CIMIT

Clinical Research Perspective

Robert J. Mayer, M.D., Professor of Medicine,
Harvard Medical School

Scientific Journal Perspective

Andrew Wechsler, M.D., Editor, *Journal of
Thoracic and Cardiovascular Surgery*

Institutional Perspective

Ronald Newbower, Ph.D., Chief Technology
Officer and Co-Founder, CIMIT

Device Industry Perspective

Christopher White, J.D., Executive Vice
President, General Counsel, AdvaMed

10:30-10:45 BREAK

10:45-12:15 PERSPECTIVES FROM GOVERNMENT
AGENCIES

Moderator, **Honorable David F. Durenberger**,
Chair, National Institute of Health Policy; Chair,
Advisory Board, MTLF
Scott Gottlieb, M.D., Deputy Commissioner for
Medical and Scientific Affairs, U.S. Food and
Drug Administration
Shirley Hicks, Director, Division of Education
& Development, Office for Human Research
Protections, U.S. Department of Health and
Human Services

12:15 LUNCH

Introduction, **Lawrence H. Cohn, M.D.**,
Professor of Cardiac Surgery, Harvard Medical
School; Division of Cardiac Surgery, Brigham &
Women's Hospital
Samuel O. Thier, M.D., Professor of Medicine
and Professor of Health Care Policy, Harvard
Medical School—on the occasion of MTLF's
10th Year

1:30 – 3:00 ECONOMICS IN THE MARKETPLACE:
BALANCING INCENTIVES FOR USE OF
TECHNOLOGY

Moderator, **Susan Bartlett Foote**, Associate
Professor, University of Minnesota; Director,
MTLF
Overview, **Fran Miller, J.D.**, Professor of Law,
Boston University School of Law; Professor of
Public Health, Boston University School of Pub-
lic Health
Risks, Rewards, and Alternatives of Gainsharing
David Nexon, Senior Executive Vice President,
AdvaMed
David Halsey, M.D., Chair, A.A.O.S. Council on
Advocacy; Chair, A.A.O.S. Board of Director's
Project Team on Gainsharing

Attendees/Program Participants

(Note: speaker names appear in bold)

Dr. Susan Alpert
*Senior Vice President - Chief Quality & Regulatory Officer
Medtronic, Inc.*

Dr. Donald Baim
*Science Chair
CIMIT*

Professor Susan Bartlett Foote, J.D.
*Director, MTLF
Associate Professor, School of Public Health
University of Minnesota*

Dr. Thomas Brady
*Director of Education
CIMIT*

Dr. Beverly Brown
*Chief Development Officer
CIMIT*

Mr. Christopher Cerone
*Vice President, Government Affairs
Zimmer, Inc.*

Mr. Blair Childs
*Managing Partner
SAS – Cleveland Clinic*

Dr. Guy Chisolm
*Vice Chair of Lerner Research Institute
Cleveland Clinic*

Dr. Hemi Chopra
*Senior Licensing Manager
Brigham & Women's Hospital*

Dr. Lawrence H. Cohn
Professor of Cardiac Surgery, Harvard Medical School; Division of Cardiac Surgery, Brigham & Women's Hospital

Mrs. Roberta Cohn

Dr. Richard Coutts
*Professor of Orthopaedic Surgery,
University of CA, San Diego;
Representative, AAOS*

Ms. Janice Crosby
*Director Business Development
CIMIT*

Mr. Mitchell Dann
*Principal
Sapient Capital*

Hon. David Durenberger
*Chair, Advisory Board
Medical Technology Leadership Forum*

Dr. Arthur Erdman
*Professor of Mechanical Engineering
University of Minnesota*

Mr. John Fernandez
*Vice President
Brigham & Women's Hospital*

Dr. Thomas Fogarty
*Clinical Professor of Surgery
Stanford University Medical Center*

Mr. Tom Glynn
*Chief Operating Officer
Partners HealthCare*

Ms. Mary Gomperts
*Director, MM Information & Transaction Systems
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Dr. Scott Gottlieb
*Deputy Commissioner for Medical & Scientific Affairs
U.S. Food & Drug Administration*

Ms. Phyllis Greenberger
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Society for Women's Health Research*

Dr. David Halsey
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AAOS Board of Directors Project Team on Gainsharing*

Mr. Ed Hedblom
*Technical Manager
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Mr. Brent Henry
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*Distinguished Professor
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Professor of Chemical Engineering
University of Minnesota*

Ms. Colleen Kigin
*Chief of Staff
CIMIT*

Mr. Craig Marinho
Boston University Law School

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